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7 March 2022

By email: s 9(2)(a)
Ref: H202200845

Dear s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 2 February 2022 for information regarding lisdexamfetamine dimesilate. Please find a response to each part of your request below.

> *1a. Could you please confirm that the Pharmac Mental Health Subcommittee notes are correct and that Vyvanse® (lisdexamfetamine dimesilate) has been classified as a Controlled Drug Class B1.*
> *1b. Please confirm the date of classification and the party that authorization this classification.*

The Pharmac Mental Health Subcommittee notes are incorrect. Lisdexamfetamine has not yet been classified as a controlled drug under the Misuse of Drugs Act 1975.

> *2a. Could you please confirm the date that the MOH approved lisdexamfetamine dimesilate as a Controlled Drug Class.*
> *2b. If this has not yet occurred, please provide the expected timing of when this will occur.*
> *3. Could you please confirm the date the Cabinet confirmed MOH classified lisdexamfetamine dimesilate as a Controlled Drug Class.*
> *3b. If this has not yet occurred, please provide the expected timing of when this will occur.*

Please see response to question one above. The process for the scheduling of controlled drugs is through a formal Order in Council as set out in section 4 of the Misuse of Drugs Act 1975. This process is currently under way. The Expert Advisory Committee on Drugs has recommended to the Minister of Health that lisdexamfetamine be classified as a class B controlled drug. The recommendation has been considered by Cabinet and Notice has been given of the making of the Misuse of Drugs (Classification and Presumption of Supply) Order 2022. The Order has now been referred to Select Committee. The timing of when the Order is made (and the Schedules to the Misuse of Drugs Act amended) is subject to Parliamentary processes.

> *4. Could you please inform me of the expected date on the communication of the updated classification status of lisdexamfetamine dimesilate to the manufacturer/ sponsor of the medication approval request, Takeda New Zealand Limited.*

Stakeholders will be advised of the formal scheduling once the Commencement Order is made by the Governor General.

> *5. What are the next steps in the process in order to receive Vyvanse in New Zealand.* s 9(2)(a) *Please note that we are happy to pay the full cost of Vyvanse if not funded by Pharmac).*

Lisdexamfetamine is currently scheduled as a prescription medicine and Vyvanse was approved in April 2021. Its availability in New Zealand is dependent on import by licensed wholesalers and there are currently no regulatory barriers preventing importation and supply of Vyvanse in New Zealand. Once lisdexamfetamine is scheduled as a controlled drug, an import licence will also be required to import.

I trust this information fufils your request. Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely

Chris James
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Medsafe